

MAY 10 1996

510(k) Summary of Safety and Effectiveness
Sharplan Lasers, Inc. Silktouch XJ Scanner CO2 Laser Accessory

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Sharplan Lasers, Inc. Silktouch XJ Scanner is based on a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which include the Coherent Computerized Pattern Generator and the Sharplan SwiftLase (aka SilkTouch) CO2 Flashscanner.

1. Sharplan Lasers, Inc.
1 Pearl Court
Allendale, NJ 07401
George J. Hattub, Director of Regulatory Affairs
Updated: October, 1995.
1-800-394-2000, ext. 531
2. **Model:** Sharplan Lasers, Inc. Silktouch XJ Scanner CO2 Laser Accessory
3. **Predicate Devices:** The Coherent Computerized Pattern Generator and the Sharplan SwiftLase (aka SilkTouch) Flashscanner.
4. **Description:** The Sharplan Lasers, Inc. Silktouch XJ Scanner CO2 Laser Accessory is a motorized, laser beam deflection system that is attached to a Sharplan CO2 laser articulating arm. The device redirects a focused laser beam from moving mirrors, within a specified pattern scan area. Similar to the common surgeon's technique of manually scanning a focused beam over a treatment area, the constantly moving beam of the Silktouch XJ Scanner limits the time of laser exposure on tissue while providing sufficient power density for tissue vaporization at low average power levels. This device features a CO2 handpiece and LCD control panel interface which allows the operator to select or change the various patterns and treatment parameters. This accessory does not defeat or over-ride the safety or control mechanisms which are integral to CO2 laser system.
5. The Sharplan Lasers, Inc. Silktouch XJ Scanner Accessory is substantially equivalent to the following devices: Coherent Computerized Pattern Generator and the Sharplan SwiftLase (aka SilkTouch) Scanner (K946304 and K941312, respectively). It is a CO2 accessory for a Sharplan Laser (models 60, 80, and 150 xj). It is indicated for soft tissue incision, excision, coagulation, vaporization, and ablation for the following indications: General/Thoracic Surgery, Neurosurgery, Otolaryngology, Dental Surgery (soft tissue only), Gynecology, Podiatry, Plastic Surgery/Dermatology, and Genito-Urinary Surgery.

No new indications were sought in this premarket notification and no clinical data was presented.

510(k) Summary of Safety and Effectiveness (continued)
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6. From a clinical performance perspective, the aforementioned devices produce a similar therapeutic output in terms of laser spot size and patterns. Regarding the technological characteristics, while are not identical, physical testing of the device has demonstrated that it is similar both in function and performance to its predicate devices. Sharplan Lasers, Inc. believes that none of the modifications made to the device raise any issues pertaining to its safety or efficacy.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.